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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,976	11/21/2003	Xuedong Song	KCX-693 (19341)	1744

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EXAMINER	
DIRAMIO, JACQUELINE A	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,976	SONG, XUEDONG	
	Examiner	Art Unit	
	JACQUELINE DIRAMIO	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-13 and 39-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-13 and 39-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Applicant's amendments to claims 1 and 12 are acknowledged.

2. Currently, claims 1 – 6, 9 – 13, and 39 – 45 are pending and under examination.

Withdrawn Objections and Rejections

3. The previous objections to claims 1 and 12 are withdrawn in view of Applicant's amendments filed October 30, 2008.

4. All previous rejections of the claims under 35 U.S.C. 103(a) are withdrawn in view of Applicant's arguments filed October 30, 2008.

Response to Arguments

5. Applicant's arguments, see pages 6-9, filed October 30, 2008, with respect to the rejection(s) of the claim(s) under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al. (WO 97/09620) in view of Jou et al. (US 5,670,381) have been fully considered and are persuasive. In particular, Applicant's argument that the resulting device from the combination of Jou et al. with Rylatt et al. would fail to generate a "compensation signal" as required by the instant claims is found persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made and presented below.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1 – 6, 9 – 13, and 39 – 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al. (WO 97/09620), as evidenced by Fitzpatrick et al. (US 6,121,008), in view of Virtanen (US 2005/0214827) and Jou et al. (US 5,670,381).

Rylatt et al. teach a flow-through assay device for detecting the presence or quantity of an analyte residing in a test sample, said flow-through assay device comprising a porous membrane 207, said porous membrane being in communication with analyte detection agents 208 (probes) and calibration agents 209 (probes), said analyte detection agents being conjugated with a specific binding partner (member) for the analyte, said porous membrane defining:

a test (detection) zone 204 within which is immobilized an analyte receptor 215 (first capture reagent), said analyte receptor being configured to bind to at least a portion of said complexes formed between the analyte and said conjugated analyte detection agents to generate a test (detection) signal having an intensity;

a procedural control (compensation) zone 212 located downstream from said test zone, wherein a binding agent is immobilized within said procedural control zone, said binding agent configured to bind to said conjugated analyte detection agents and complexes formed between the analyte and said conjugated analyte detection agents passing through said test zone to generate a control (compensation) signal having an intensity; and

a calibration zone(s) 211 within which a calibration agent receptor 214 (second capture reagent) is immobilized, said calibration agent receptor being configured to bind to said calibration agents to generate a calibration signal that is substantially constant relative to the intensities of said test signal and said control signal, said calibration zone being positioned between said test zone and said procedural control zone;

wherein the amount of analyte within the test sample is proportional to the ratio of said test signal intensity to said control signal intensity, as calibrated by said calibration signal intensity (see Figure 2a; p7, lines 25-29; p8, lines 20-29; p10, lines 27-30; p12, lines 25-30; p14, lines 2-19; p15, lines 11-12; and Example 1).

With respect to the limitation of Applicant's claim 1 reciting "wherein the intensity of said compensation signal is inversely proportional to the intensity of said detection signal," the signal generated in the control zone of Rylatt et al. would create a signal that is inversely proportional to the intensity of the test signal because the control zone is binding to the unbound conjugated detectable labels, wherein the amount of unbound detectable labels would be inversely proportional to the amount of analyte in the test sample. Since the test zone is binding to the complexes created between the analyte and the detectable label, the test signal would be proportional to the amount of analyte in the sample. Therefore, the control signal created in the

control zone of Rylatt et al. would in fact be inversely proportional to the test signal created in the test zone (see Fitzpatrick et al.: column 2, lines 19-67; and column 3, lines 1-9).

However, Rylatt et al. fail to teach that the binding agent immobilized in the procedural control zone (compensation zone) comprises a polyelectrolyte, wherein said polyelectrolyte has a net charge opposite to that of the detection agents (probes).

Virtanen teaches an assay device and method for binding to and detecting an analyte of interest. The assay device and method utilizes signal responsive moieties, wherein these moieties comprise light reflecting and/or scattering particles, such as metal or colloidal metal particles, or dyed plastic particles, including latex particles. In biological applications, the signal responsive moiety, particularly gold or latex microspheres, will preferably be coated with detergents or derivatized so that they will have a surface charge. This is done to prevent the attachment of these particles nonspecifically with surfaces or with each other (see Abstract; and paragraphs [0167]-[0174]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Rylatt et al. the coating or derivatizing of their detectable labels, particularly the colloidal metal or latex particles, to create a surface charge as taught by Virtanen because Virtanen teaches the benefit of coating or derivatizing a signal responsive moiety, particularly gold or latex microspheres, so that they will have a surface charge when using the signal moieties in biological assay applications, in order to prevent the attachment of these particles nonspecifically with surfaces or with each other.

Jou et al. teach a device for performing an ion-capture assay comprising a porous membrane that includes a diffusive capture reagent comprising a specific binding member for the

analyte of interest conjugated to a first charged substance; and a reaction zone comprising an immobilized second charged substance. By contacting the device with a sample containing an analyte of interest, a first complex is formed between the analyte and capture reagent. This complex binds to the immobilized second charged substance in the reaction zone through ion-capture, wherein the second charged substance is oppositely charged with respect to the charged substance of the analyte complex. The charged substance(s) preferably comprises an anionic or cationic polymeric substance (polyelectrolyte), which enables the production of a generic solid phase device for use in specific binding assays. Assay procedures for many different analytes can use the same solid phase material which contains a predetermined zone of anionic or cationic capture polymer rather than an immobilized binding member capable of binding only a specific analyte as found in conventional flow-through or test-strip devices. Further, the ion-capture technique increases the potential number of complexes that can be immobilized on the solid support (see column 6, lines 25-59; column 7, lines 1-45; column 10, lines 13-65; column 19, lines 29-67; column 22, lines 29-62; column 26, lines 51-67; and column 28, lines 1-44).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device and labels of Rylatt et al. and Virtanen an immobilized polyelectrolyte as the binding agent in the procedural control zone, as opposed to a specific binding member, as taught by Jou et al. because Jou et al. teach the benefit of immobilizing anionic and/or cationic polymeric substances in a capture zone on a porous support for binding to charged conjugated analyte binding reagents because the polymeric substances allow for the binding of the charged conjugated reagents or complexes thereof to a solid phase support material through ion-capture, which increases the potential number of complexes that

can be immobilized on the solid support and allows for the production of a generic solid phase device, wherein many different analytes can use the same solid phase material which contains a predetermined zone of anionic or cationic capture polymer rather than an immobilized binding member capable of binding only a specific receptor as found in conventional flow-through or test-strip devices. In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the binding reagent in the procedural control zone of Rylatt et al. with the polyelectrolyte taught by Jou et al. because this change is a mere alternative and a functionally equivalent capturing technique. One having ordinary skill in the art would have been motivated to make such a change since only the expected labeling effect would have been obtained, and changes such as these are routinely made based on the economics and availability of components.

With respect to Applicant's claims 2-4 and 42, Rylatt et al. teach that the analyte detection agents can comprise a fluorophore (luminescent compound), a chemiluminescent molecule, a chromogen, a radioisotope, or a direct visual label, such as a colloidal metal or a latex particle (see p8, lines 22-29).

With respect to Applicant's claims 5 and 44, Rylatt et al. teach that the specific binding partner is preferably an antibody (see Example 1).

With respect to Applicant's claims 6 and 45, Rylatt et al. teach that the analyte receptor (first capture reagent) preferably comprises an antibody (see Example 1).

With respect to Applicant's claims 9 and 11, Jou et al. teach that the charged polymeric substance (polyelectrolyte) can be anionic or cationic (see column 7, lines 1-46; and column 19, lines 29-36).

With respect to Applicant's claim 10, Jou et al. teach various charged polymers for the polyelectrolyte, which include combinations of those recited in Applicant's claim 10 (see column 19, lines 29-67; and column 20, lines 1-67).

With respect to Applicant's claim 12, Rylatt et al. teach that the calibration agent receptor (second capture reagent) and calibration agent can comprise streptavidin and biotin (see Example 1).

With respect to Applicant's claim 13, Rylatt et al. teach that the device can comprise a sandwich-type assay device (see Example 1).

With respect to Applicant's claims 39 – 41, both Rylatt et al. and Jou et al. teach the direct or indirect and covalent or non-covalent attachment of reagents, or polyelectrolyte, to the surface of the porous membrane, as well as the use of spacer molecules (functional groups) to bind the receptor reagents to the porous membrane (see p11, lines 12-18 of Rylatt et al; and column 28, lines 1-13 of Jou et al).

With respect to Applicant's claim 43, the combination of Rylatt et al. in view of Jou et al. would result in the binding agent of the procedural control (compensation) zone of Rylatt et al. being substituted with the polyelectrolyte of Jou et al., which would result in the procedural control zone being free of biological capture reagents.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
May 4, 2009